IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

Palmetto Pharmaceuticals LLC, Plaintiff, v. AstraZeneca Pharmaceuticals LP, Defendant.	Case No. 2:11-cv-00807-SB-JDA **REPORT AND RECOMMENDATION OF MAGISTRATE JUDGE**

This matter is before the Court on Defendant's motions to dismiss for failure to state a claim or, alternatively, for summary judgment. [Docs. 14, 41.] Pursuant to the provisions of Title 28, United States Code, Section 636 and Local Rule 73.02(C)(7), D.S.C., this magistrate judge is authorized to review pretrial motions and submit findings and recommendations to the District Court in cases referred for pretrial management.

This is an action for patent infringement under 35 U.S.C. § 281, and the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338. The Court has reviewed the pleadings and briefs submitted by the parties, as well as the applicable law. For the reasons given below, the Court recommends (1) Defendant's first motion to dismiss [Doc. 14] be deemed moot and (2) Defendant's subsequent motion to dismiss [Doc. 41] be (a) granted as to Plaintiff's claims of direct infringement under 35 U.S.C. § 271(a) and contributory infringement under 35 U.S.C. § 271(c) and (b) denied as to Plaintiff's claims of induced infringement under 35 U.S.C. § 271(b) and willful infringement.

PROCEDURAL HISTORY

On April 5, 2011, Plaintiff filed its Complaint against Defendant, alleging infringement of U.S. Patent No. 6,465,516, entitled "Method of Stimulating Nitric Oxide Synthase." [Doc. 1.] On April 26, 2011, Defendant filed a motion to dismiss for failure to state a claim or, in the alternative, for summary judgment. [Doc. 14.] On May 16, 2011, Plaintiff filed an Amended Complaint[1] [Doc. 27] as well as a response in opposition to Defendant's motion to dismiss [Doc. 28].

On May 26, 2011, Defendant filed a reply to Plaintiff's response [Doc. 39], and on June 15, 2011, Defendant filed a subsequent motion to dismiss for failure to state a claim or, in the alternative, for summary judgment [Doc. 41]. Plaintiff filed a response in opposition to Defendant's subsequent motion to dismiss on July 19, 2011. [Doc. 44.] Defendant filed a reply on August 19, 2011. [Doc. 47.] On November 15, 2011, this action was referred, by Order of the Honorable Sol Blatt, Jr., to the undersigned for pretrial management. [Doc. 51.] Defendant's motion to dismiss or, alternatively, for summary judgment [Doc. 41] is now ripe for review.

[1] Because the Amended Complaint superseded the original Complaint, the Court recommends denying as moot Defendant's initial motion to dismiss [Doc. 14]. *See Young v. City of Mount Ranier*, 238 F.3d 567, 573 (4th Cir. 2001) (stating that "an amended pleading ordinarily supersedes the original and renders it of no legal effect" (citation omitted)); *Hall v. Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am., UAW*, 2011 WL 4014315, at *1 (W.D.N.C. June 21, 2011) (*citing Colin v. Marconi Commerce Sys. Emps.' Ret. Plan*, 335 F. Supp. 2d 590, 614 (M.D.N.C. 2004); *Turner v. Kight*, 192 F. Supp. 2d 391, 397 (D. Md. 2002)) (denying as moot the defendants' motions to dismiss because the second amended complaint rendered moot the defendants' pending motions to dismiss, which were related to the superseded complaint); *McCoy v. City of Columbia*, 2010 WL 3447476, at *1–2 (D.S.C. Aug. 31, 2010) (adopting the magistrate judge's report and recommendation to the extent it recommended that the motion to dismiss be found as moot because the amended complaint superseded the original complaint and rendered any attack upon it moot).

BACKGROUND

The '516 Patent

Plaintiff, a small, privately funded company headquartered in Charleston, South Carolina, is engaged in pharmaceutical research in the southeastern United States. [Doc. 27 ¶ 1.] Plaintiff is the assignee and lawful owner of U.S. Patent No. 6,465,516, which issued on October 15, 2002, as amended by Reexamination Certificate No. 6,465,516 C1, which issued on issued on April 5, 2011 (collectively "the '516 patent"). [*Id.* ¶ 6.] The '516 patent claims a method of treating nonhyperlipidemic subjects, i.e., people who do not have hyperlipidemia,[2] who would benefit from increased nitric oxide ("NO") production. [*Id.* ¶ 7.] Claim 1 of the '516 patent, the sole independent claim, claims the following:

> 1. A method for treating a *nonhyperlipidemic* subject who would benefit from increased Nitric Oxide production in a tissue comprising:
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> administering to the *nonhyperlipidemic* subject in need of such treatment **[**, irrespective of the subject's cholesterol level,**]** a Hmg-CoA reductase inhibitor in an amount effective to increase Nitric Oxide production in said tissue of the subject.[3]

[Doc. 27-2 at 16.]

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[2] As Plaintiff explains in its Complaint,

> Hyperlipidemia is a medical condition that usually includes having a high cholesterol level. Persons who are nonhyperlipidemic do not have high cholesterol levels. High cholesterol levels are considered to be abnormal.

[Doc. 27 ¶ 8.]

[3] As indicated in the reexamination certificate, italics indicate additions made to the patent and brackets indicate matter that appeared in the patent but has been deleted and is no longer part of the patent. [Doc. 27-2 at 16.]

CRESTOR® and Its Label/Package Insert

In 2003, Defendant began marketing a statin, rosuvastatin calcium, under the trademark CRESTOR®, which has become a widely prescribed statin. [Doc. 27 ¶ 13.] Also in 2003, the United States Food & Drug Administration ("FDA") approved CRESTOR® for three uses, or indications, including the treatment of people with hyperlipidemia and, within that group, people with elevated cholesterol levels. [*Id.* ¶ 14.] Moreover, in 2003, Defendant began enrolling patients in a clinical trial, known as the JUPITER Trial, to evaluate whether people who did not have hyperlipidemia, but who did have cardiovascular risk factors, could benefit from taking CRESTOR®. [*Id.* ¶¶ 15–16.] On February 8, 2010, the FDA approved the use of CRESTOR® for indications resulting from the JUPITER Trial. [*Id.* ¶ 25.] Following its approval, the FDA announced on its website: "This is the first time CRESTOR has been approved for use in the prevention of heart disease in individuals with 'normal' low-density lipoprotein (LDL) cholesterol levels and no clinically evident heart disease." [*Id.*]

In the package insert accompanying CRESTOR®, Defendant instructs,

> In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥50 years old in men and ≥60 years old in women, [high sensitivity C-reactive protein ("hsCRP")] ≥2mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CRESTOR is indicated to:
>
> - reduce the risk of stroke
> - reduce the risk of myocardial infarction
> - reduce the risk of arterial revascularization procedures

[*Id.* ¶ 44.] Scientific publications in the field of cardiovascular disease establish that administering a statin to a person with elevated hsCRP is administering a statin to a person in need of increased NO production. [*Id.* ¶ 29.] Namely, peer-reviewed scientific publications establish (1) decreased NO production is implicated in all known cardiovascular disease, (2) elevated hsCRP is associated with reduced NO production, and (3) statins can increase NO production in people with elevated hsCRP. [*Id.* ¶ 30; *see* ¶¶ 31–35.] Thus, the CRESTOR® package insert instructs doctors, other medical professionals, users, and potential users of CRESTOR® that using CRESTOR® for the primary prevention of cardiovascular disease benefits nonhyperlipidemic individuals. [*Id.* ¶ 45.] Therefore, Plaintiff alleges treating a nonhyperlipidemic individual having an elevated hsCRP by administering CRESTOR® is treating a subject who would benefit from increased NO production by administering an Hmg-CoA reductase inhibitor in an amount effective to increase NO production. [*Id.* ¶ 46.]

Plaintiff's Infringement Claims

Plaintiff alleges Defendant has had actual knowledge of the '516 patent since at least November 2008 and is aware that the use of CRESTOR® infringes at least claims 1, 4, 7, and 15–20 of the '516 patent. [*Id.* ¶ 47; *see also* ¶¶ 40–41 (alleging that in November 2008 Plaintiff offered Defendant the opportunity to license or acquire the '516 patent but Defendant declined the offer in December 2008).] Plaintiff asserts claims of (1) direct infringement [*id.* ¶¶ 50–53]; (2) indirect infringement by contributing to infringement by doctors and others [*id.* ¶¶ 61–64]; (3) indirect infringement by inducing doctors and others to infringe [*id.* ¶¶ 54–60]; and (4) willful infringement [*id.* ¶¶ 65–66].

Specifically, Plaintiff alleges Defendant directly infringes the '516 patent by providing CRESTOR® to nonhyperlipidemic individuals who would benefit from increased NO production. [*Id.* ¶ 52.] Plaintiff also alleges the '516 patent is directly infringed by the provision of CRESTOR® to nonhyperlipidemic subjects who would benefit from increased NO production by, inter alia, doctors, other medical professionals, and/or patients. [*Id.* ¶ 55.] Further, Plaintiff alleges that, through the label/package insert, website, and promotional materials for CRESTOR®, Defendant instructs the public, including nonhyperlipidemic individuals who would benefit from increased NO production, to use CRESTOR® in an infringing manner, and to contact their physicians or other medical professionals to seek CRESTOR® for use in an infringing manner. [*Id.* ¶ 56.] Plaintiff also alleges Defendant's label/package insert, website, and funded publications instruct and encourage doctors and/or other medical professionals to prescribe and/or provide for CRESTOR® in a way that when so used infringes the '516 patent. [*Id.* ¶ 57.] Moreover, Plaintiff alleges Defendant employs pharmaceutical sales specialists in South Carolina who encourage doctors and/or other medical professionals to prescribe and/or provide CRESTOR® in a way that when so used infringes the claims of the '516 patent. [*Id.* ¶ 58.] Further, Plaintiff alleges Defendant has knowledge of the '516 patent and that the use indicated and promoted on its label infringes the claims of the '516 patent. [*Id.* ¶ 59.] Based on this knowledge and action, Plaintiff claims Defendant intentionally encourages this infringing use. [*Id.*]

APPLICABLE LAW

Motion to Dismiss Standard

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a motion to dismiss for failure to state a claim should not be granted unless it appears certain that the plaintiff can prove no set of facts which would support its claim and would entitle it to relief. When considering a motion to dismiss, the court should "accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff ." *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir.1993).[4] Further, on a motion pursuant to Rule 12(b)(6), if matters outside the pleadings are presented to and not excluded by the court, the motion is treated as one for summary judgment under Rule 56 of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 12(d).

With respect to well-pleaded allegations, the Supreme Court explained the interplay between Rule 8(a) and Rule 12(b)(6) in *Bell Atlantic Corp. v. Twombly*:

> Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the "grounds" of his "entitle[ment] to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).

[4] In patent cases, courts apply the law of the regional circuits, rather than that of the Federal Circuit, to procedural issues such as the elements of a motion to dismiss. *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1355–56 (Fed. Cir. 2007) (citing *C & F Packing Co., Inc. v. IBP, Inc.*, 224 F.3d 1296, 1306 (Fed. Cir. 2000)).

550 U.S. 544, 555 (2007) (internal footnote and citations omitted); *see also E. Shore Mkts., Inc. v. J.D. Assocs., Ltd. P'ship*, 213 F.3d 175, 180 (4th Cir. 2000) (noting that court "need not accept as true unwarranted inferences, unreasonable conclusions, or arguments"); 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1216, at 235–36 (3d ed. 2004) ("[T]he pleading must contain something more . . . than a bare averment that the pleader wants compensation and is entitled to it or a statement of facts that merely creates a suspicion that the pleader might have a legally cognizable right of action.").

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). The plausibility standard reflects the threshold requirement of Rule 8(a)(2)—the pleader must plead sufficient facts to show he is entitled to relief, not merely facts consistent with the defendant's liability. *Twombly*, 550 U.S. at 557 (quoting Fed. R. Civ. P. 8(a)(2)); *see also Iqbal*, 129 S. Ct. at 1949 ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of "entitlement to relief."'" (quoting *Twombly*, 550 U.S. at 557)).[5]

[5] As stated above, if matters outside the pleadings are presented to and not excluded by the court, a motion to dismiss is treated as one for summary judgment under Rule 56. Fed. R. Civ. P. 12(d). Here, to the extent the parties have presented to the Court matters outside the pleadings, the Court has excluded such extraneous matters and considered Defendant's motion as a motion to dismiss under Rule 12(b)(6).

DISCUSSION

Direct Infringement Claim

Plaintiff alleges Defendant directly infringes the '516 patent by providing CRESTOR® to nonhyperlipidemic individuals. [Doc. 27 ¶ 52.] As explained below, Plaintiff has failed to adequately allege a claim for direct infringement by Defendant.

As set forth in the statute defining patent infringement, a party directly infringes a patent if the party, "without authorization[,] makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor." 35 U.S.C. § 271(a). A patent claiming a method, such as the '516 patent, "is directly infringed only by one practicing the patented method," *Joy Techs. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) (emphasis omitted), which requires actual performance of all of the steps of the patented method, either by the infringer or by one under the infringer's direction and control, *see, e.g.*, *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379–81 (Fed. Cir. 2007); *see also Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325,1334–35 (Fed. Cir. 2008) (holding the defendant was not liable for direct infringement of a method patent, even though it sold software containing instructions to perform the patented process, because the software did not actually perform the process); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008) (discussing the standard developed in *BMC Resources* for whether a method claim is directly infringed by the combined actions of multiple parties). Thus, with respect to a patent claiming a method, a plaintiff may establish a direct infringement claim by alleging (1) the defendant actually performed all steps of the patented method or (2) one

or more parties under the defendant's direction and control actually performed all steps of the patented method.

Here, Plaintiff has failed to allege Defendant performs every step of the patented method. As previously stated, Plaintiff alleges Defendant directly infringes the '516 patent by *providing* CRESTOR® to nonhyperlipidemic individuals. However, Claim 1, which is the only independent claim of the '516 patent, recites the step of *administering*, not *providing*.[6] To "administer" is

> 1 : to manage or supervise the execution, use, or conduct of <*administer* a trust fund>
>
> 2 a : to mete out : dispense <*administer* punishment>
>
> b : to give ritually <*administer* the last rites>
>
> c : to give remedially <*administer* a dose of medicine>

[6] The Court held a telephonic conference with the parties on December 6, 2011 to determine whether a *Markman* hearing could be held to construe the term "administering," which the Court found would be determinative of its decision on direct infringement. As the Federal Circuit Court of Appeals has stated,

> *Markman* does not require a district court to follow any particular procedure in conducting claim construction. It merely holds that claim construction is the province of the court, not a jury. To perform that task, some courts have found it useful to hold hearings and issue orders comprehensively construing the claims in issue. Such a procedure is not always necessary, however. If the district court considers one issue to be dispositive, the court may cut to the heart of the matter and need not exhaustively discuss all the other issues presented by the parties. District courts have wide latitude in how they conduct the proceedings before them, and there is nothing unique about claim construction that requires the court to proceed according to any particular protocol. As long as the trial court construes the claims to the extent necessary to determine whether the accused device infringes, the court may approach the task in any way that it deems best.

Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1358 (Fed. Cir. 2001). Here, the parties agreed there was no need to hold a *Markman* hearing on the limited issue of the definition of "administering." The parties further agreed their briefings and common use of the term provided sufficient guidance for the Court to construe the term "administering." Therefore, the parties did not request a full *Markman* hearing on this term, and the Court construes the term pursuant to the guidance provided by the parties' briefs and the common definitions of the term.

Administer Definition, Merriam-Webster.com, http://www.merriam-webster.com/dictionary/administer (last visited Dec. 28, 2011). Alternatively, to "provide" is

> 1 *archaic* : to prepare in advance
>
> 2 a : to supply or make available (something wanted or needed) <*provided* new uniforms for the band>; *also* : afford <curtains *provide* privacy>
>
> b : to make something available to <*provide* the children with free balloons>
>
> 3 : to have as a condition : stipulate <the contract *provides* that certain deadlines will be met>

Provide Definition, Merriam-Webster.com, http://www.merriam-webster.com/dictionary/provide (last visited Dec. 28, 2011). By comparing these two definitions, it is clear that *providing* is not the same as *administering*, and thus, Plaintiff has failed to adequately plead Defendant performs each step of the patented method because Plaintiff has failed to plead Defendant performs the step of administering. Accordingly, Plaintiff has failed to set forth a plausible claim of direct infringement.

Moreover, Plaintiff has failed to plead Defendant exercised direction and control over one or more third parties who actually performed all steps of the patented method. Within its claim of direct infringement, Plaintiff alleges only that Defendant directly infringed the '516 patent by providing CRESTOR® to nonhyperlipidemic individuals; Plaintiff makes no allegations as to Defendant's direction and control over third parties who practice the method claimed in the '516 patent. [*See* Doc. 27 ¶¶ 50–53.] However, in an abundance of caution, the Court has considered the Amended Complaint in its entirety to determine whether Plaintiff has pled sufficient facts to state a plausible claim that Defendant

exercised the requisite direction and control over third parties to be liable for direct infringement.

The Federal Circuit has stated that

> where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises "control or direction" over the entire process such that every step is attributable to the controlling party, i.e., the "mastermind." At the other end of this multi-party spectrum, mere "arms-length cooperation" will not give rise to direct infringement by any party.
>
> . . .
>
> Under *BMC Resources*, the control or direction standard is satisfied in situations where the law would traditionally hold the accused direct infringer vicariously liable for the acts committed by another party that are required to complete performance of a claimed method.

Muniauction, 532 F.3d at 1329–30 (citing *BMC Res.*, 498 F.3d at 1379–81). Here, Plaintiff has failed to allege Defendant had any sort of direction or control over third parties performing steps of the patented method to the extent that Defendant would be vicariously liable for the acts committed by those third parties; Plaintiff merely alleges Defendant instructs doctors, other medical professionals, and/or the public to use CRESTOR® in an infringing manner [*see, e.g.*, Doc. 27 ¶¶ 44–45]. Accordingly, Plaintiff has failed to plead facts sufficient to raise a right to relief for direct infringement by Defendant above a speculative level, and Plaintiff's claim pursuant to § 271(a) should be dismissed.

Contributory Infringement Claim

The elements of contributory infringement under 35 U.S.C. § 271(c) are defined in the statute:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Additionally, to prevail on a claim of either contributory infringement or inducing infringement, the plaintiff must prove that direct infringement of the patent has occurred.[7] *See, e.g.*, *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009) (quoting *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1312 (Fed. Cir. 2005)); *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1312 (Fed. Cir. 2007) (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304–05 (Fed. Cir. 2002)). Thus, to adequately plead contributory infringement under § 271(c), a patent owner must allege facts plausibly showing that (1) there is direct infringement; (2) the alleged infringer had knowledge of the patent; (3) the component, material, or apparatus has no substantial noninfringing uses; and (4) the component, material, or apparatus is a material part of the invention. *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010) (citing 35 U.S.C. § 271(c)).

[7] "Although not directly infringing, a party may still be liable for inducement or contributory infringement of a method claim if it sells infringing devices to customers who use them in a way that directly infringes the method claim." *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1379 (Fed. Cir. 2005). For purposes of deciding this motion, the Court will assume, without deciding, that the '516 patent is infringed when a nonhyperlipidemic patient takes CRESTOR® because Defendant does not dispute that CRESTOR®, when taken in recommended dosages, is effective to increase NO production in the tissue of the patient, as recited in Claim 1 of the '516 patent. Defendant disputes Plaintiff's allegations only with respect to *Defendant's* role in direct infringement of the '516 patent.

Plaintiff alleges Defendant contributorily infringes the '516 patent because Defendant "sells and offers to sell in the United States a material— CRESTOR—with a package insert containing instructions indicating and promoting use of CRESTOR in [a] manner that infringes claims of the [] '516 patent." [Doc. 27 ¶ 62.] Plaintiff further alleges CRESTOR® and its package inserts are especially made and intended for a use that infringes the claims of the '516 patent and are not a staple article or commodity of commerce suitable for noninfringing use. [*Id.* ¶ 63.] However, Plaintiff also alleges that "CRESTOR has become a widely prescribed statin" and that CRESTOR® was originally approved for three indications, including the treatment of hyperlipidemic persons. [*Id.* ¶¶ 13–14.]

Because Plaintiff has pled that Defendant's component, material, or apparatus has substantial noninfringing uses, Plaintiff has failed to state a claim for relief based on contributory infringement by Defendant. If the parties do not dispute that the accused component, material, or apparatus is capable of noninfringing use, "the question of contributory infringement turns on whether the non-infringing use is substantial." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). A noninfringing use is "substantial" when it is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Id.*; *see also i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010) (affirming the jury's finding that the defendant engaged in contributory infringement, in light of evidence that the accused product's noninfringing use "was not a practical or worthwhile use for the [consumers] for which the [accused device] was designed and marketed").

Here, Plaintiff has pled CRESTOR® has become a widely prescribed statin, and from 2003–2010, CRESTOR® was approved only for the treatment of hyperlipidemic persons. [Doc. 27 ¶¶ 13–14, 25.] The '516 patent claims only a method for treating *non*hyperlipidemic persons; therefore, the treatment of hyperlipidemic persons through the administration of CRESTOR® is clearly noninfringing. Moreover, that CRESTOR® is widely prescribed and was approved for only noninfringing use for seven years demonstrates the noninfringing use is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327. Further, Plaintiff has failed to allege CRESTOR® is no longer prescribed for the treatment of hyperlipidemic persons, and the label/package insert indicates noninfringing uses for CRESTOR®. [Doc. 41-4 at 1 (listing seven indications, including an indication for "patients with primary hyperlipidemia")]; *Darcangelo v. Verizon Commc'ns, Inc.*, 292 F.3d 181, 195 n.5 (4th Cir. 2002) (holding that in ruling on a motion to dismiss, it was proper for the district court to consider an agreement relied on in the complaint even though the agreement was not contained in the complaint but was attached by the defendant to its memorandum in support of its motion to dismiss). Accordingly, the Court finds there are substantial noninfringing uses for CRESTOR®. Because Plaintiff's allegations effectively state there are substantial noninfringing uses for CRESTOR® and its label/package insert, Plaintiff cannot establish at least one element of a claim of contributory infringement—that the component, material, or apparatus has no substantial noninfringing uses—and consequently, Plaintiff has failed to state a plausible claim for relief based on contributory infringement. Therefore, Plaintiff's contributory infringement claim should be dismissed.

Induced Infringement Claim

Section 271(b) provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Even if a party is not liable for direct infringement, the party may be liable "for inducement [of] infringement of a method claim if it sells infringing devices to customers who use them in a way that directly infringes the method claim." *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1379 (Fed. Cir. 2005). To establish inducement, a patent owner must show that the accused infringer induced the infringing acts and knew or should have known that its actions would induce actual infringement. *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc). To prove such specific intent, a plaintiff must come forward with "[e]vidence of 'active steps . . . taken to encourage direct infringement,' such as advertising an infringing use or instructing how to engage in an infringing use, [which] show[s] an affirmative intent that the product be used to infringe." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005) (citing with approval patent law in copyright case) (quoting *Oak Indus., Inc. v. Zenith Elecs. Corp.*, 697 F. Supp. 988, 992 (N.D. Ill. 1988)); *see Rodime PLC v. Seagate Tech., Inc*., 174 F.3d 1294, 1306 (Fed. Cir. 1999) ("Inducement requires proof that the accused infringer knowingly aided and abetted another's direct infringement of the patent."). The requisite intent to induce infringement may be demonstrated through circumstantial evidence. *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (citing *Moleculon Res. Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986)).

Plaintiff, in its Amended Complaint, alleges the '516 patent is directly infringed by doctors, other medical professionals, and/or patients, and Defendant—through its package inserts, promotional materials, website, and sales representatives—instructs these third parties how to use CRESTOR® in an infringing manner. [Doc. 27 ¶¶ 55–59.] Plaintiff alleges Defendant had knowledge of the '516 patent, had knowledge that the use indicated on the CRESTOR® label infringes the claims of the '516 patent, and intentionally encouraged this infringing use. [*Id.* ¶ 59.] Plaintiff further alleges these acts constitute active inducement of infringement of the '516 patent. [*Id.* ¶ 60.]

If the label/package insert instructs doctors and/or users to perform the patented method, the label/package insert *may* provide evidence of Defendant's affirmative intent to induce infringement. *See Vita-Mix*, 581 F.3d at 1329 n.2 ("The question is not . . . whether a user following the instructions may end up using the device in an infringing way. Rather, it is whether [the] instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent."); *see also Grokster*, 545 U.S. at 940 n.13 ("It is not only that encouraging a particular consumer to infringe a copyright can give rise to secondary liability for the infringement that results. Inducement liability goes beyond that, and the distribution of a product can itself give rise to liability where evidence shows that the distributor intended and encouraged the product to be used to infringe. In such a case, the culpable act is not merely the encouragement of infringement but also the distribution of the tool intended for infringing use."); *DSU Med.*, 471 F.3d at 1306 ("[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the

direct infringer's activities." (citing *Grokster*, 545 U.S. at 936–37; *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990))). As described above, Plaintiff alleges the label/package insert accompanying CRESTOR® instructs,

> In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥50 years old in men and ≥60 years old in women, [high sensitivity C-reactive protein ("hsCRP")] ≥2mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CRESTOR is indicated to:
>
> - reduce the risk of stroke
> - reduce the risk of myocardial infarction
> - reduce the risk of arterial revascularization procedures

[Doc. 27 ¶ 44.] Plaintiff further alleges scientific publications in the field of cardiovascular disease establish that administering a statin to a person with elevated hsCRP is administering a statin to a person in need of increased NO production [*id.* ¶ 29], and thus, the CRESTOR® package insert instructs doctors, other medical professionals, users, and potential users of CRESTOR® that using CRESTOR® for the primary prevention of cardiovascular disease benefits nonhyperlipidemic individuals [*id.* ¶ 45]. Therefore, Plaintiff alleges treating a nonhyperlipidemic individual having an elevated hsCRP by administering CRESTOR® is treating a subject who would benefit from increased NO production by administering an Hmg-CoA reductase inhibitor in an amount effective to increase NO production. [*Id.* ¶ 46.]

Defendant argues Plaintiff has not sufficiently alleged Defendant had (1) knowledge that the induced acts would infringe the '516 patent or (2) the specific intent to induce

others to infringe. [Doc. 41-1 at 13.] Specifically, Defendant asserts Plaintiff's argument is nothing more than conclusory assertions regarding various publications to infer that Defendant implicitly provides instructions to infringe the '516 patent. [Doc. 41-1 at 19.] At the pleading stage, however, Plaintiff does not have to allege direct evidence of intent; circumstantial evidence will suffice. Therefore, when these allegations are measured against the elements of active inducement discussed above, the Court concludes they are sufficient under *Twombly* and *Iqbal* to plausibly state a claim for relief. Accordingly, the Court recommends Plaintiff's claim of induced infringement survive Defendant's motion to dismiss.

Willful Infringement Claim

Because the Court recommends Plaintiff's claim of induced infringement go forward, the Court also recommends Plaintiff's claim of willful infringement survive Defendant's motion to dismiss. In its memorandum in support of its motion to dismiss, Defendant argues that "if the Court finds that *all three* of [Plaintiff's] counts for infringement should be dismissed, there can be no finding of willful infringement and Count IV should be dismissed." [Doc. 41-1 at 27 (emphasis added).] Thus, Defendant has argued Plaintiff's claim of willful infringement be dismissed only if the Court dismisses all three of Plaintiff's claims of direct and indirect infringement; Defendant failed to argue Plaintiff's claim of willful infringement be dismissed if some of Plaintiff's claims of direct and indirect infringement go forward.[8] Accordingly, because the Court recommends that Plaintiff's

[8] In its response in opposition to Defendant's motion to dismiss, Plaintiff merely argues it has adequately pled direct, indirect, and willful infringement and, like Defendant, has provided no guidance as to whether Plaintiff's claim of willful infringement should survive Defendant's motion to dismiss if the Court determines some but not all of Plaintiff's claims of direct and indirect infringement should go forward.

claim of induced infringement survive Defendant's motion to dismiss, the Court also recommends Plaintiff's claim of willful infringement go forward.

CONCLUSION AND RECOMMENDATION

Wherefore, based on the foregoing, it is recommended that (1) Defendant's original motion to dismiss [Doc. 14] be DENIED as MOOT and (2) Defendant's subsequent motion to dismiss [Doc. 41] be GRANTED as to Plaintiff's claims of direct infringement under 35 U.S.C. § 271(a) and contributory infringement under 35 U.S.C. § 271(c) and DENIED as to Plaintiff's claims of induced infringement under 35 U.S.C. § 271(b) and willful infringement.

IT IS SO RECOMMENDED.

s/Jacquelyn D. Austin
United States Magistrate Judge

January 4, 2012
Greenville, South Carolina